K082173 page 1 of 2

Cordis
a Johnson & Johnson company

AUG 25 2008

# 510(k) Summary

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| **Submitter** | Cordis Corporation, a Johnson & Johnson Company<br>7 Powder Horn Drive<br>Warren, New Jersey 07059 |
| **Contact Person** | Karen Wilk<br>Regulatory Affairs Manager<br>Phone: 908-412-7257<br>Fax: 908-412-3008 |
| **Date Summary Prepared** | August 20, 2008 |

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| **General Information** | Trade Name: **Micro Guide Catheter XP**<br>Common/Usual Name: Percutaneous Catheter<br>Device Classification: Class II, 21 CFR 870.1250<br>Catheter, Percutaneous<br>Product Code: DQY |

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| **Name of Predicate Devices** | The device is substantially equivalent to:<br>• Cordis Micro Guide Catheter XP (510(k) # K035335)<br>• Cordis Vista Brite Tip® Guiding Catheter (510(k) #K021593) |

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| **Device Description** | The Micro Guide Catheter XP is a single lumen, braided guide catheter with a PTFE liner. The Micro Guide Catheter has a 4.5 French profile, an inner diameter of 0.042" and overall lengths of 82 cm and 132 cm.<br><br>The Micro Guide Catheter XP is provided sterile (via Ethylene Oxide sterilization) and is intended for single use only. |

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| **Indication for Use** | The Micro Guide Catheter XP accessory is to be used with the Frontrunner® XP CTO Catheter. The Frontrunner XP CTO Catheter is intended to facilitate the intraluminal placement of conventional guide wires beyond the stenotic lesions (including chronic total occlusions) in the peripheral vasculature prior to further percutaneous intervention. |
| **Summary of Testing and Conclusion** | The Micro Guide Catheter XP is substantially equivalent to the predicate devices. The substantial equivalence to the predicate devices has been demonstrated via data collected from non-clinical *in-vitro* bench testing.<br><br>Biocompatibility testing was conducted per ISO 10993-1 (2003)(E): "Biological Evaluation of Medical Devices. Part 1: Evaluation and Testing'. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Cordis Corporation
Ms. Karen Wilk
Regulatory Affairs Manager
7 Power Horn Drive
Warren, NJ 07059

Re: K082143
Trade/Device Name: Micro Guide Catheter XP
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: PDU
Dated: July 29, 2008
Received: July 30, 2008

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Dear Ms. Wilk:

This letter corrects our substantially equivalent letter of August 25, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

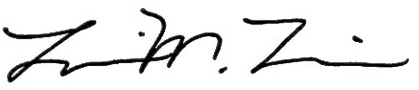
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K082143

Device Name: Frontrunner Micro Guide Catheter XP

Indication for Use: The **Micro Guide Catheter XP** accessory is to be used with the Frontrunner® XP CTO Catheter. The Frontrunner XP CTO Catheter is indicated to facilitate the intraluminal placement of conventional guidewires beyond the stenotic lesions (including chronic total occlusions) in the peripheral vasculature prior to further percutaneous intervention.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K082143